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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|------------------|
| 10/579,356 | 12/03/2007 | Polly Gregor | D6547 | 7507 |
| 7590 | 02/23/2010 | | EXAMINER | |
| Benjamin Aaron Adler Adler & Associates 8011 Candle Lane Houston, TX 77071 | | | WEHBE, ANNE MARIE SABRINA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
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| | | | DELIVERY MODE | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/579,356 | GREGOR ET AL. | |
| | Examiner | Art Unit | |
| | Anne Marie S. Wehbe | 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10, 21-27 and 34-48 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) ____ is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) 1-10, 21-27, and 34-48 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's preliminary amendment filed on 5/12/06 canceled claims 11-20, 28-33, and 49-76. Claims 1-10, 21-27, and 34-48 are currently pending in the instant specification.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 10, 21-22, and 24-25, drawn to a composition comprising a vector comprising a nucleic acid sequence encoding a tumor associated antigen, and methods of inducing an antitumor immune response comprising the administration of said composition.

Group II, claim(s) 1, 3-10, 21-22, and 24-25 drawn to a composition comprising a vector comprising a nucleic acid encoding a tumor endothelial marker 8 or fragment thereof, and methods of inducing an antitumor immune response comprising the administration of said composition.

Group III, claim(s) 1-10, and 21-25, drawn to a composition comprising one or more vectors comprising a nucleic acid sequence encoding a tumor associated antigen, and a nucleic acid encoding a tumor endothelial marker 8 or fragment thereof, and methods of inducing an antitumor immune response comprising the administration of said composition.

Group IV, claim(s) 26-27, drawn to a method of inducing an antitumor immune response comprising administration of dendritic cells comprising a vector comprising a nucleic acid sequence encoding a tumor associated antigen.

Group V, claim(s) 26-27, drawn to a method of inducing an antitumor immune response comprising administration of dendritic cells comprising a vector comprising a nucleic acid sequence encoding a tumor endothelial marker 8 or fragment thereof.

Group VI, claim(s) 26-27, drawn to a method of inducing an antitumor immune response comprising administration of dendritic cells comprising a vector a nucleic acid sequence

encoding a tumor associated antigen, and a nucleic acid encoding a tumor endothelial marker 8 or fragment thereof.

Group VII, claim(s) 26-27, drawn to a method of inducing an antitumor immune response comprising administration of dendritic cells comprising a tumor associated antigen protein.

Group VIII, claim(s) 26-27, drawn to a method of inducing an antitumor immune response comprising administration of dendritic cells comprising a tumor endothelial marker 8 protein or fragment thereof.

Group IX, claim(s) 26-27, drawn to a method of inducing an antitumor immune response comprising administration of dendritic cells comprising a tumor associated antigen protein and a tumor endothelial marker 8 protein or fragment thereof.

Group X, claim(s) 34-48, drawn to a composition comprising a vector comprising a nucleic acid encoding a tumor associated antigen and a tumor endothelial marker 8 protein or fragment thereof, and methods of inducing an antitumor immune response comprising the administration of said composition.

Group XI, claim(s) 34-35, and 44-48, drawn to a composition comprising a vector comprising a nucleic acid encoding a tumor endothelial marker 8 or fragment thereof and a tumor associated antigen protein, and methods of inducing an antitumor immune response comprising the administration of said composition.

Group XII, claim(s) 34-42, 44-45, and 48, drawn to a composition comprising a tumor associated antigen protein and a tumor endothelial marker 8 protein or fragment thereof, and methods of inducing an antitumor immune response comprising the administration of said composition.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there is no single technical feature that links all the Groups. For example, the vector encoding a tumor associated antigen of Group I is not required for the inventions of Groups II, VII-IX, and XI-XII. It is further noted that although some groups are linked by the technical feature of a vector encoding a tumor associated antigen, or a vector encoding a tumor endothelial marker 8, neither vector constitutes a “special technical feature” as the prior art teaches both such compositions, see for example Hurpin et al. (1998) Vaccine, Vol.

16 (2/3), 208-215. who teaches a plasmid vector encoding the tumor associated antigen p53 and methods of administering the plasmid encoding p53 to generate anti-tumor immune responses, and US 2003/0148410, which teaches vectors encoding TEM-8 (tumor endothelial marker 8) and their use as vaccines for colon cancer.

In addition, please note that 37 CFR 1.475 states that an international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

From the above, it is clear that multiple combinations are not allowed. Further, the allowed combinations do not include multiple products, and multiple methods of using said product, as claimed in the instant application, see MPEP § 1850 and 37 CFR 1.475. Further, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

Please note as well that although Groups I and II, for example, can be related as subcombinations useable together, and Groups I and III, or II and III, for example, can be related as subcombination/combination, no special technical feature exists to show unity of invention as discussed above, and each of the subcombinations can be used in multiple combinations as evidenced by the presence of the composition of Group I, for example, in the combination compositions of Groups III, VI, and X.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not

available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/
Primary Examiner, A.U. 1633